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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,087	01/02/2004	Michael E. Hawkins	0103-0039 (ZM0570)	1328

43231 7590 05/04/2006

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EXAMINER

RAMANA, ANURADHA

ART UNIT PAPER NUMBER

3733

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/751,087	Applicant(s) HAWKINS, MICHAEL E.	
	Examiner Anu Ramana	Art Unit 3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 1/2/04.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |                                                                                                                                              |                                                                                         |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                                                  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/19/05</u> . | 6) <input type="checkbox"/> Other: _____                                                |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 7-8, 10-12 and 18-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Cloutier (US 4,207,627).

Cloutier discloses an implant for replacing opposed articulating bone ends including: a first femoral component 3 and a second tibial component 5 wherein tibial component 5 has means for low friction articulation, i.e., bearing members 7 and 9, with femoral component 3 and an intercondylar portion or "eminence" 33 or "means for engaging" the femoral component 3, the intercondylar portion 33 being mechanically joined with the means for low friction articulation (col. 4, lines 31-68, col. 5 and col. 6, lines 1-53).

Regarding claims 7 and 8, Cloutier discloses that the tibial platform (33, 37 and 39) is made of the same material as the femoral component 3, i.e., chromium-cobalt steel alloy, and that the bearing members 7 and 9 are made of plastic.

It is noted that intercondylar portion 33 inherently has a higher toughness than the bearing members 7 and 9.

Claims 19-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Grundei (US 4,711,639).

Grundei discloses a tibial implant including first and second plastic bearing portions 6 and a metallic intercondylar portion, including tray 1 and tibial eminence 5 interposed between them forming three separate subcomponents joined together to form a single component (Fig. 4, col. 2, lines 27-68 and col. 3, lines 1-36). It is noted

that the plastic bearing portions inherently have a smaller toughness value than the metallic intercondylar portion.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 11-12 and 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wyss (US 2004/0002767 A1) in view of Krebs et al. (US 6,365,089).

Wyss discloses a femoral or "first" component 12, a tibial or "second" component 16 wherein component 16 includes a first portion with a bearing surface (43) and a second portion 18 including an intercondylar region (57, 59) (paras [0025]-[0032]).

Wyss discloses all elements of the claimed invention except for: (1) the material of construction of the prosthesis; and (2) the intercondylar region having a second predetermined toughness value greater than a first predetermined toughness value of the bearing surface.

Krebs et al. teach radiation treatment of a UHMWPE tibial insert to provide improved wear and abrasion properties wherein selective shielding of the stabilizing post or "intercondylar region" can be employed to maintain higher toughness of the intercondylar region (col. 7, lines 37-64).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have constructed the tibial component 16 of UHMWPE or polyethylene and the post 18 of UHMWPE, polyethylene or polyketone, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have crosslinked the bearing surface of the Wyss tibial component while shielding the intercondylar region, as taught by Krebs et al., to improve wear resistance while maintaining higher mechanical properties in the intercondylar region which experiences higher mechanical shear force.

Claims 1-5, 10-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robie et al. (US 6,126,692) in view of Krebs et al. (US 6,365,089).

Robie et al. disclose a tibial insert 14 made of ultrahigh molecular weight polyethylene wherein insert 14 includes a first portion with a bearing surface (52a, 52b) and a second portion including an intercondylar region 50 wherein the first and second portions are permanently joined at the time of manufacture (Fig. 1 and col. 3, lines 42-58).

Robie et al. disclose all elements of the claimed invention except for the intercondylar region having a second predetermined toughness value greater than a first predetermined toughness value of the first portion.

Krebs et al. teach radiation treatment of a UHMWPE tibial insert to provide improved wear and abrasion properties wherein selective shielding of the stabilizing post or "intercondylar region" can be employed to maintain higher toughness of the intercondylar region (col. 7, lines 37-64).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have crosslinked the bearing surface of the Robie et al. insert while shielding the intercondylar region, as taught by Krebs et al., to improve wear resistance while maintaining higher mechanical properties in the intercondylar region which experiences higher mechanical shear force.

Claims 11-12, 14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volz (US 4,257,129) in view of Krebs et al. (US 6,365,089).

Volz discloses a tibial bearing component including a first portion 22 with a bearing surface and a second portion 40 having an intercondylar region wherein the first

and second portions are joined together interoperatively by a pin 23 (Figs. 1 and 2, col. 3, lines 49-68 and col. 4, lines 1-63).

Regarding claim 15, Volz discloses that the first and second portions are joined by a dovetail projection engaging a dovetail slot (col. 5, lines 29-49).

Volz discloses all elements of the claimed invention except for: (1) the first portion being made of relatively highly crosslinked polyethylene or "a first predetermined toughness value"; and (2) the second portion being made of a relatively lightly crosslinked polyethylene or "a second predetermined toughness value" wherein the second toughness value is higher than the first toughness value.

Krebs et al. teach radiation treatment of a UHMWPE tibial insert to provide improved wear and abrasion properties wherein selective shielding of the stabilizing post or "intercondylar region" can be employed to maintain higher toughness of the intercondylar region (col. 7, lines 37-64).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have crosslinked the bearing surface of the Volz insert while shielding the intercondylar region, as taught by Krebs et al., to improve wear resistance while maintaining higher mechanical properties in the intercondylar region which experiences higher mechanical shear force.

Regarding claim 17, Volz discloses that the second portion is made of a biologically inert material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the second portion of UHMWPE, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use, herein biocompatibility, as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cloutier (US 4,207,627).

Cloutier discloses all elements of the claimed invention except for the tibial platform being made of ceramic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the tibial platform of ceramic , since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AR   
April 30, 2006